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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/501,187 | 01/13/2006 | Rhonda Hansen | 20366-124US1 | 3472 |

7590 01/04/2011

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| EXAMINER | |
|---|---|
| GIBBS, TERRA C | |
| ART UNIT | PAPER NUMBER |
| 1635 | |
| MAIL DATE | DELIVERY MODE |
| 01/04/2011 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/501,187 | HANSEN, RHONDA | |
| | Examiner | Art Unit | |
| | TERRA C. GIBBS | 1635 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21-26,28,29 and 31-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-26, 28, 29, and 31-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

This Office Action is a response to Applicant's Amendment and Remarks filed October 20, 2010.

Claim 27 has been canceled. Claims 21, 28, 29, 32-34, 37, and 39 have been amended.

Claims 21-26, 28, 29, and 31-39 are pending in the instant application.

Claims 21-26, 28, 29, and 31-39 have been examined on the merits as detailed below:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Priority***

In the previous Office Action mailed July 20, 2010, it was noted the instant claims have been afforded priority to filing date of the instant application which is 1/13/2006 because Provisional Application 60345637 and PCT/US03/00657 did not support the term, "DKFZp56611233". In Applicant's Amendment filed October 20, 2010, Applicants have amended the claims to recite the term, "DKFZp566I1233". In view of this Amendment, the instant claims have been afforded priority to Provisional Application 60345637, filed January 8, 2002.

***Claim Rejections - 35 USC § 112***

In the previous Office Action mailed July 20, 2010, claims 1-29 and 31-39 were

rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. **This rejection is moot** against claim 27 in view of Applicant's Amendment filed October 20, 2010 to cancel this claim. **This rejection is withdrawn** against claims 21-26, 28, 29, and 31-39 in view of Applicant's Amendment filed October 20, 2010 to recite the term, "DKFZp566I1233".

***Claim Rejections - 35 USC § 102***

In the previous Office Action mailed July 20, 2010, claims 21-26 and 31-35 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. PreGrant Publication 20030124128 (made of record in the previous Office Action mailed February 17, 2010). **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed July 20, 2010.

***Response to Arguments***

In response to this rejection, Applicants argue that U.S. PreGrant Publication 20030124128 is not available as art under §102(e) because the priority date of the instant application is January 8, 2002 and the priority documents from which U.S. PreGrant Publication 20030124128 claims priority to do not disclose the gene corresponding to DKFZp566I1233 and therefore, do not support subject matter related to DKFZp566I1233.

This argument has been fully considered, but is not found persuasive because it is noted that U.S. PreGrant Publication 20030124128:

Claims priority from Provisional Application 60299887, filed 06/21/2001
Claims priority from Provisional Application 60301572, filed 06/27/2001
Claims priority from Provisional Application 60306501, filed 07/18/2001
Claims priority from Provisional Application 60325002, filed 09/25/2001
Claims priority from Provisional Application 60362585, filed 03/05/2002
Claims priority from Provisional Application 60380391, filed 05/14/2002

Now then, referring to at least Provisional Application 60299887 and Provisional Application 60301572, these Applications disclose the gene corresponding to DKFZp566l1233. See Table 1, marker M110, and SEQ ID NOs: 68 and 69. It is noted that SEQ ID NO:69 is 100% identical to SEQ ID NO:512 of Applicant's invention.

Therefore, and contrary to Applicant's assertions, in view of the fact that the priority documents from which U.S. PreGrant Publication 20030124128 claims priority to disclose the gene corresponding to DKFZp566l1233, U.S. PreGrant Publication 20030124128 anticipates claims 21-26 and 31-35.

***Claim Rejections - 35 USC § 103***

In the previous Office Action mailed July 20, 2010, claims 21-29, 31-34, and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/60860 A2 (made of record in the previous Office Action mailed February 17, 2010) in view of WO 01/12662 A2 (made of record in the previous Office Action mailed February 17, 2010). **This rejection is moot** against claim 27 in view of Applicant's Amendment filed October 20, 2010 to cancel this claim. **This rejection is maintained** against claims 21-26, 28, 29, 31-34, and 37-39 for the reasons of record set forth in the previous Office Action mailed July 20, 2010.

***Response to Arguments***

In response to this rejection, Applicants argue that WO 01/60860 does not disclose that DKFZp566I1233 is differentially expressed in cancer cells. For example, Applicants contend that WO 01/60860 makes clear that the disclosed genes associated with prostate cancer are listed in Table 1-9. Applicants argue that SEQ ID NO:29252 of WO 01/60860 is not found in Tables 1-9 and therefore, the reference fails to teach or suggest that SEQ ID NO:29252 (i.e. DKFZp566I1233) is differentially expressed in cancer cells. Applicants contend without such a teaching, one of skill in the art would have had no reason to modify the teachings of the WO 01/60860 application.

This argument has been fully considered, but is not found persuasive because although WO 01/60860 does not teach that SEQ ID NO:29252 is found in Tables 1-9, WO 01/60860 does teach that the nucleic acid compositions of their invention are used for assessing the cancerous state of prostate cells. See pages 13-15, 24, 25, and 28, for example.

Additionally, the Examiner acknowledges that WO 01/60860 does not explicitly teach that SEQ ID NO:29252 (DKFZp566I1233) is a marker found in Tables 1-9. However, the secondary reference of WO 01/12662 teaches that SEQ ID NO:54 (DKFZp566I1233) is a marker that can be used in methods for screening a compound for effectiveness in modulating expression of a target polynucleotide. See page 32, for example. WO 01/12662 teaches that the activity of SEQ ID NO:54 (DKFZp566I1233) in the presence of a test compound is compared with the activity of SEQ ID NO:54 (DKFZp566I1233) in the absence of the test compound. WO 01/12662 teaches that a

change in the activity of SEQ ID NO:54 (DKFZp566I1233) in the presence of the test compound is indicative of a compound that modulates the activity of SEQ ID NO:54 (DKFZp566I1233). WO 01/12662 teaches that the expression of SEQ ID NO:54 (DKFZp566I1233) is determined in a normal or standard and, with respect to cancer, the expression levels are determined and are used to indicate a predisposition for disease. See pages 35, 46, 52, 55, and 56, for example.

Applicants next argue that WO 01/12662 does not provide a specific teaching that modulating the activity or level or expression of SEQ ID NO:54 (DKFZp566I1233) affects a cancerous phenotype. Applicants also argue that WO 01/12662 does not provide any examples of agents that modulate cancerous phenotype by modulating the activity or expression of SEQ ID NO:54 (DKFZp566I1233).

These arguments have been fully considered, but are not found persuasive because while it is acknowledged that WO 01/12662 does not explicitly teach that modulating the activity or level of expression of SEQ ID NO:54 (DKFZp566I1233) affects a cancerous phenotype, WO 01/12662 does indeed provide examples of agents that modulate activity or expression of SEQ ID NO:54 (DKFZp566I1233) in cancer cells. See page 9, 12, and 46, for example.

Applicant is reminded that the burden of establishing whether the prior art has the further function of affecting a cancerous phenotype under generally any assay conditions falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either

anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting *In re Best* 195 USPQ 430 as per above. Also, see *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986). Therefore, it falls to Applicant to determine and provide evidence that the examples of agents that modulate activity or expression of DKFZp566l1233 in cancer cells disclosed by WO 01/60860 and WO 01/12662 A2 would or would not have the additional functional limitation of modulating cancerous phenotype as claimed in Applicant's invention.

Applicants next argue that WO 01/12662 teaches that DKFZp566l1233 is expressed in squamous carcinoma tumor samples, but not breast cancer cells. Applicants point the Examiner to Table 4 at page 98.

This argument has been fully considered, but is not found persuasive because WO 01/12662 teaches that MEMAP expression is associated with breast cancer cells.

See pages 38, and 51. Also see Table 4 at pages 97, 98, 100, and 102, for example.

WO 01/12662 also discloses:

> Various modifications and variations of the described methods and systems of the invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with certain embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments.

Applicants next argue that WO 01/12662 fails to teach or suggest that DKFZp566l1233 is differentially expressed in cancer cells and that modulating the activity or level of expression of DKFZp566l1233 affects a cancerous phenotype, and therefore, one of skill in the art would have had no reason to combine or modify the teachings of WO 01/12662 with the teachings of WO 01/60860 to arrive at Applicant's invention.

This argument has been fully considered, but is not found persuasive. WO 01/60860 teaches novel genes associated with prostate cancer. WO 01/60860 teaches teach that compositions of their invention are used for assessing the cancerous state of prostate cells. While it is noted that WO 01/60860 does not identify SEQ ID NO:29252 (DKFZp566l1233) as a marker specifically found in Tables 1-9, WO 01/60860 does teach that the nucleic acid compositions of their invention are used for assessing the cancerous state of prostate cells. Furthermore, the secondary reference of WO 01/12662 identifies SEQ ID NO:54 (DKFZp566l1233) as a marker that can be used to determine differential expression of DKFZp566l1233 in tissues and samples. WO 01/12662 also identifies said tissue and samples as breast cancer cells and non-breast cancer cells.

Therefore, given the combined teachings of WO 01/60860, along with WO 01/12662, one of skill in the art would be motivated to combine the teachings of WO 01/12662 with the teachings of WO 01/60860 to arrive at Applicant's invention.

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In the previous Office Action mailed July 20, 2010, claims 35 and 36 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/60860 A2 in view of WO 01/12662 A2 as applied to claims 21-29, 31-34, and 37-39, and further in view of U.S. Patent No. 6,844,325 ('325) (of record). **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed July 20, 2010.

***Response to Arguments***

In response to this rejection, Applicants argue that U.S. Patent No. 6,844,325 fails to remedy the deficiencies of WO 01/60860 or WO 01/12662 since U.S. Patent No. 6,844,325 relates primarily to various clones over-expressed in breast cancer tumor tissues, none of which include DKFZp566I1233. Applicants contend that U.S. Patent No. 6,844,325 fails to teach methods of identifying or screening for a cancer therapeutic that modulates a cancerous phenotype by modulating the biological activity or level of expression of DKFZp566I1233 differentially expressed in a cancerous cell.

This argument has been fully considered, but is not found persuasive because as discussed *supra*, WO 01/60860 teaches novel genes associated with prostate cancer. WO 01/60860 teaches teach that compositions of their invention are used for assessing

the cancerous state of prostate cells. While it is noted that WO 01/60860 does not identify SEQ ID NO:29252 (DKFZp566l1233) as a marker specifically found in Tables 1-9, WO 01/12662 identifies SEQ ID NO:54 (DKFZp566l1233) as a marker that can be used to determine differential expression of DKFZp566l1233 in tissues and samples. WO 01/12662 also identifies said tissue and samples as breast cancer cells and non-breast cancer cells.

U.S. Patent No. 6,844,325 was relied upon to teach that a sequence comprising at least 12 contiguous nucleotides of SEQ ID NO:513 or an antisense polynucleotide comprising a nucleotide sequence of SEQ ID NO:508 of Applicant's invention were known in the prior art. See clone 21053 (SEQ ID NO:458). U.S. Patent No. 6,844,325 taught that nucleotides of their invention are in the antisense orientation.

As noted in the previous Office Action mailed July 20, 2010, at pages 18 and 19, it is noted that 6,844,325 is silent regarding whether the cDNA sequence represented by SEQ ID NO:458 could be used as an antisense to specifically inhibit DKFZ expression. However, the burden of establishing whether the prior art antisense cDNA could be used to inhibit gene expression under generally any assay conditions falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing

that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting *In re Best* 195 USPQ 430 as per above. Therefore, it falls to Applicant to determine and provide evidence that prior art antisense cDNA disclosed by 6,844,325 would or would not inhibit DKFZ gene expression as instantly claimed.

Therefore, one of ordinary skill in the art would have been motivated to use a DKFZ antisense polynucleotide comprising a nucleotide sequence of SEQ ID NO:508 or a sequence comprising at least 12 contiguous nucleotides of SEQ ID NO:513 since 6,844,325 taught that such a sequence could be used as an antisense oligonucleotide.

In view of the foregoing, when all the evidence is considered, the totality of the rebuttal evidence of non-obviousness fails to outweigh the evidence of obviousness made of record. Thus, it is maintained that the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was filed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached from 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Heather Calamite can be reached on 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

December 31, 2010
/Terra Cotta Gibbs/

/Sean R McGarry/
Primary Examiner, Art Unit 1635